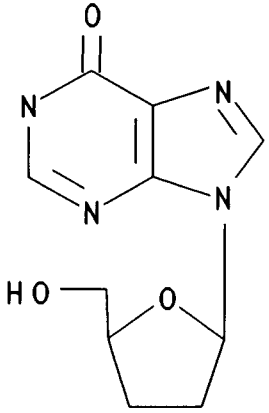
DIDEOXYINOSINE

NSC - 612049

The following information applies to the injectable dosage form of dideoxyinosine manufactured by the National Cancer Institute.



Chemical Name: 2', 3'-Dideoxyinosine

Other Names: ddI, Videx®, didanosine (USAN)

CAS Registry Number: 69655-05-6

Molecular Formula: $C_{10}H_{12}N_4O_3$ **M.W.:** 236.2

How Supplied: Sterile, 250 mg, vial: supplied as a white lyophilized powder with sodium hydroxide to adjust pH.

Solution Preparation: 250 mg/vial : When constituted with 16.5 mL of 0.9% Sodium Chloride Injection, USP, each milliliter of solution contains 15 mg of dideoxyinosine with sodium hydroxide to adjust to pH 6.0 to 8.5. Shake the vial vigorously for two to three minutes to insure complete dissolution.

Storage: Store the intact vials under refrigeration (2-8 °C).

Stability: Shelf-life surveillance of the intact vials is ongoing. Two lots of ddI were stable at room temperature (22-25 °C) for four years, and stable at elevated temperature (50 °C) for one year.

Constitution as directed results in a solution that is physically and chemically stable for at least five days at room temperature and at 37 °C. After eight hours storage at 4 °C, crystals formed in the constituted solution. The crystals redissolved with warming to ambient temperature and with vigorous shaking for about three minutes.

Further dilution to a concentration of 0.45 mg/mL in 0.9% Sodium Chloride Injection, USP, or 5% Dextrose Injection, USP, in glass, PVC, or polyolefin containers yielded the following stability results:

Percentage of Initial Dideoxyinosine[a] Remaining in Solution

Diluent	Temp (°C)	Container	Days 1	5	14
D5W[b]	25	glass	92	62	23
		PVC	76	28	4
	4	glass	97	94	89
		PVC	92	85	71
NS[c]	25	glass	97	96	93
		PVC	97	98	94
		polyolefin	103	103	96
	4	glass	100	98	99
		PVC	100	98	99

(a) Initial dideoxyinosine concentration 0.45 mg/mL.
(b) 5% Dextrose Injection, USP
(c) 0.9% Sodium Chloride Injection, USP

CAUTION: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Inline filtration of a 0.5 mg/mL solution in 0.9% Sodium Chloride, USP, in a PVC bag, did not cause any drug loss during a simulated four-hour infusion through a 0.22 μm filter.

Route of Administration: Intravenous